Supreme Court, U.S.
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No. 04-

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether liability can be imposed for willfully inducing patent infringement under 35 U.S.C. § 271(b) based solely on evidence that a party has disseminated a basic scientific fact to others.

2. Whether an express limitation in a patent claim can be ignored so as to allow the patent to cover the exact opposite of what was claimed.

3. Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

Petitioner in this case is Laboratory Corporation of America Holdings (doing business as LabCorp) ("LabCorp").

LabCorp has no parent corporations. Wellington Management Company, L.L.P., a publicly held mutual fund, owns ten percent or more of LabCorp's stock. No other publicly held company owns ten percent or more of LabCorp's stock.

Respondents are Metabolite Laboratories, Inc. and Competitive Technologies, Inc.

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Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

Petitioner Laboratory Corporation of America Holdings ("LabCorp") respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the Federal Circuit is reported at 370 F.3d 1354 and is reproduced at page 1a of the appendix to this petition ("App."). The order of the District Court denying LabCorp's motion for judgment as a matter of law or a new trial is unreported and is reproduced at App. 34a.

JURISDICTION

The judgment of the Federal Circuit was entered on June 8, 2004. On August 5, 2004, the Federal Circuit denied a

timely filed petition for rehearing or rehearing en banc. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutes are set forth in the appendix to this brief.

INTRODUCTION

The holding of the Federal Circuit in this case is truly extraordinary. The court construed a patent to confer on respondents a legally-protected monopoly to bar any doctor in the Nation from even *thinking* about a well-known scientific correlation. It then went even further, holding—in conflict with other Federal Circuit decisions—that petitioner LabCorp indirectly "induced" such infringement merely by publishing truthful information informing doctors of this basic scientific fact. And further compounding its errors, the Federal Circuit violated well-established tenets of patent law by expanding the patent beyond its express terms, and by upholding its validity.

This case implicates a well-recognized and intractable conflict in the lower court. And the case is of substantial national importance, given the severe threat to patient care posed by the Federal Circuit's holding that a party can violate the patent laws merely by informing doctors of a basic medical fact critical to treatment decisions. The conflict has necessarily engendered nationwide confusion, and the Federal Circuit has not been able to reconcile the conflict on its own. If this Court does not intervene, the result will be continuing and intolerable uncertainty for patent holders, practitioners, and those in LabCorp's position who seek to disseminate basic medical facts needed to ensure the health of the Nation's populace. The Court should therefore grant certiorari to resolve the conflicts on these important issues.

STATEMENT OF THE CASE

A. The '658 Patent.

This case involves Patent No. 4,940,658 (the "Patent"), which seeks a legally-protected monopoly over the thought

processes of doctors. Specifically, the patent claims a right to prevent doctors from *thinking* about a scientific correlation used for patient care. The correlation relates to homocysteine, an amino acid found naturally in blood serum. The Patent's "inventors" assert that they were the first to discover a connection between elevated levels of total homocysteine in body fluids and possible deficiencies in two basic vitamins, vitamin B12 (cobalamin) and folic acid (folate).

It is disputed whether the inventors were in fact the first to notice this correlation. But there is no dispute that, well before they applied for their patent, it was well-known that elevated levels of homocysteine correlated with other conditions. Most important, it had been known since at least 1969 —more than 15 years before the filing of the Patent application—that elevated homocysteine was connected to increased risk of heart disease. *See, e.g.*, A4828-29.[1] Elevated homocysteine has also been connected with other conditions, including renal disease, dehydration, vitamin B6 deficiency, inborn enzyme deficiencies, hypothyroidism, lupus, pregnancy-related conditions, and decreased cognitive function. *See, e.g.*, A8377, A8430. And respondent Competitive Technologies, Inc. ("CTI") has itself noted that elevated levels are also associated with Alzheimer's disease, chronic fatigue syndrome, and rheumatoid arthritis. *See* A7977.

The Patent primarily claims a new method for assaying homocysteine levels in bodily fluids, which requires the use of gas chromatography and mass spectrometry ("GCMS"). *See* A929, col. 41, lns. 2-57. That method, which is described in Claims 1-12 of the Patent, is not at issue in this appeal. LabCorp has paid and *continues* to pay royalties whenever it uses the patented assay method. A4744-46.[2]

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[1] "A___" refers to the Appendix filed in the Court of Appeals.

[2] The Patent is now owned by CTI. CTI licensed the Patent to respondent Metabolite Laboratories, Inc. ("Metabolite"), which in turn sublicensed to LabCorp's predecessor certain Metabolite

This case arises because the Patent also claimed a much broader monopoly. The disputed claim in this case, Claim 13, seeks to patent the basic scientific connection between elevated homocysteine levels and the possibility of certain vitamin deficiencies. In its entirety, Claim 13 seeks to patent

> [a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

App. 3a.

Claim 13 is thus a "method" patent consisting of only two steps. *First*, one must assay a body fluid for an elevated level of total homocysteine. It does not matter what assay method is used, for Claim 13 applies no matter how one tests for homocysteine. *Second*, one must "correlat[e]" the elevated level of homocysteine with a deficiency of cobalamin or folate. The term "correlating" is not further defined, and nothing in the patent says precisely what it means to "correlate" an elevated level of homocysteine with vitamin deficiencies. The entire second step was added to overcome a prior art rejection based on Section 102 of the Patent Act. *See* A973, 975.

Respondents, however, have shown how broadly they interpret Claim 13. It is their theory that, unless a license is granted and a royalty paid, every one of the thousands of doctors who orders one of the millions of homocysteine tests performed for patients nationwide necessarily infringes the Patent because the doctor looks at the test result and

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technology relating to performing "licensed assays" that "us[ed] methods and materials falling within the claims of [the '658 patent]." A7952.

allegedly *thinks* that the result *might* indicate something about the existence or non-existence of a vitamin deficiency. Under respondents' theory—now endorsed by the Federal Circuit—when a doctor orders a test and then thinks in his or her mind about the possible connection between the test result and a vitamin deficiency, that doctor has infringed the Patent by performing the patented "correlating" step.

B. LabCorp's Performance of Homocysteine Tests.

Respondents have also taken their claim further yet. LabCorp is the Nation's second largest laboratory testing company. Rather than sue every doctor for infringement for *thinking* about a possible indication of a vitamin deficiency when reviewing a test result, respondents sued LabCorp—which indisputably committed no direct infringement—on the theory that LabCorp contributes to or induces infringement by performing homocysteine tests for doctors and by allegedly informing doctors of the basic medical fact that elevated homocysteine is connected to vitamin deficiencies.

LabCorp has performed two different types of homocysteine tests. One is a "panel test" that assays for homocysteine along with three other metabolites. LabCorp pays royalties to respondents when it performs this test because this test employs the patented GCMS method. *See* A4744-45. LabCorp also performs a "single homocysteine test" that assays just for homocysteine. Initially, LabCorp also used the CGMS method for this test, and thus paid royalties to respondents.

Unlike the panel test, the single homocysteine test is of limited utility to doctors screening for vitamin deficiencies. That is because, as the Patent itself notes, homocysteine may be elevated in cases of cobalamin *or* folate deficiency, *or* as the result of other conditions, and a test *only* for homocysteine therefore cannot itself diagnose specific vitamin deficiencies. A911, col. 5, lns. 45-48, 64-66, A4293, 4825. The patent specification itself notes that it could be "extremely dangerous" to diagnose and treat a cobalamin or folate defi-

ciency based on just an elevated homocysteine result. *See* A909, col. 1, lns. 46-55. Indeed, one of the '658 inventors wrote to LabCorp in 1992 advising that it was not good medical practice to use a single metabolite—such as homocysteine—to diagnose cobalamin or folate deficiencies. A7950.

Single homocysteine tests *are* useful, however, in screening patients for risk of heart disease. It was discovered as early as 1969 that there is a link between elevated levels of homocysteine and increased risk of heart disease. *See* A8374, A7980, A8010, A8029. This medical knowledge became more widespread by the 1990s and resulted in an increase in demand for tests solely of homocysteine. *See* A5141, A5144.

In May 1998, LabCorp entered into a research agreement with Abbott Laboratories to test Abbott's new immunoassay method for assaying for homocysteine. Abbott's method was faster and less labor-intensive than the GCMS method identified in the Patent—a crucial advance in light of the increased demand for single homocysteine tests.

As a result, in 1998 LabCorp stopped using the licensed method for single homocysteine blood tests and began using Abbott's method. *See* A8519.[3] LabCorp continued, however, to use respondent CTI's licensed method to perform the panel test and homocysteine assays on urine samples, and it continued to pay royalties on those assays. A4744-45. On November 2, 1998, LabCorp notified respondent Metabolite (CTI's licensee) that it had begun using the Abbott method for single homocysteine assays, and that it would no longer pay royalties for such tests. A8473.

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[3] The sublicense agreement specifically provides that LabCorp could terminate the agreement with respect to licensed assays of homocysteine if "a more cost effective commercial alternative is available that does not infringe a valid and enforceable claim of the Licensed Patents." A7957.

C. District Court Proceedings.

In 1999, CTI and Metabolite sued LabCorp for direct and indirect infringement of the Patent and for breach of the sublicense agreement. A102.[4] Plaintiffs alleged that LabCorp's performance of single homocysteine tests using the Abbott immunoassay method infringed Claim 13. *See* A2404.

The District Court issued a pre-trial order interpreting Claim 13. A219. The court defined "elevated" as "raised above the normal range." A220. The court defined "correlating" as meaning "to establish a mutual or reciprocal relationship between," further observing that " '[c]orrelating' is a verb, and must * * * comprise a discrete, sequential process step." A221. The court subsequently granted summary judgment to LabCorp on direct infringement because LabCorp itself did not do any "correlating" of test results. A1. But the court denied LabCorp's motion for summary judgment on induced infringement. A2.

The case was tried to a jury beginning in November 2001. The court denied LabCorp's motion for JMOL at the close of the evidence, candidly informing counsel that the jury was "probably going to flip a coin." A5406. The jury returned a verdict against LabCorp for contributory and induced infringement. And while the trial evidence demonstrated that fewer than 20% of test results showed *elevated* homocysteine levels (as expressly required to satisfy the limitations of Claim 13), App. 32a-33a, the jury nonetheless awarded damages to plaintiffs based on *every* single homocysteine test LabCorp performed. That amounted to $1,019,365.01 to CTI on its patent claim, and $3,652,724.61 to Metabolite on its breach of contract claim. A5-6. The jury also found LabCorp's infringement to be willful, and returned a verdict in favor of plaintiffs on LabCorp's invalidity defenses. A6-7.

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[4] CTI, the patent holder, sued LabCorp for patent infringement, Metabolite, the licensee, sued LabCorp for breach of contract.

In November 2002, the District Court denied LabCorp's post-trial motion for JMOL or a new trial, and doubled the jury's patent damages award. App. 36a. The court also enjoined LabCorp from performing "*any* homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method." App. 38a (emphasis added and internal quotation omitted).

D. Court of Appeals Decision.

1. Claim Construction. A panel of the Federal Circuit affirmed by a 2-1 vote. As an initial matter, LabCorp had contended that for the "correlating" step to have any real meaning, it must require a physician to confirm that a patient with elevated homocysteine is in fact suffering from a vitamin deficiency as evidenced by actual physical symptoms. LabCorp explained that the patent itself notes that many people with elevated homocysteine do *not* suffer from vitamin deficiencies, and that the "inventors" themselves had determined such deficiencies in their patients by looking for physical symptoms. A910-911. Thus, because respondents presented no evidence that doctors who look at the results of single homocysteine tests ever confirm the existence of vitamin deficiencies, LabCorp argued that the doctors did not infringe the patent and that LabCorp could not be held liable for induced or contributory infringement.

The panel rejected this argument, holding that Claim 13

> does not require a further association between the level of total homocysteine and [physical symptoms]. *The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies.*

App. 8a (emphasis added). *See also* App. 12a ("the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms").

In other words, the court held that a doctor infringes the patent merely by looking at a test result and *thinking* in his or her mind that there is an "association of homocysteine levels with vitamin deficiencies." App. 8a. Once the doctor has thought about this basic scientific association after looking at a homocysteine test result, he or she has performed the patented "correlation." According to the court, no further steps—such as confirming that the patient actually *has* a vitamin deficiency—are required to infringe the patent.

Then, the Federal Circuit expanded the patent even further. Whereas Claim 13 clearly states that it covers only the assaying and correlation of "an *elevated* level of total homocysteine," A929 (emphasis added), the panel majority held that the patent is infringed even by test results that are *not* elevated—more than 80% of all test results. The majority held that it is immaterial whether a test result is elevated because the accepted definition of "correlating" is to establish a "mutual or reciprocal" relationship. In so holding, however, the court ignored the clear language of the patent requiring correlation only of *elevated* levels. App. 12a.

Judge Schall dissented on this point. In his view, by holding that the Patent is infringed by the correlation of test results showing *unelevated* homocysteine levels, "the majority impermissibly expand[ed] the scope of claim 13 beyond the actual words of the claim." App. 29a. As he explained, "[t]here is no language in Claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency." App. 31a. Thus, "[i]f the patient's homocysteine levels are not 'elevated,' by the plain language of the claim, there is no 'correlating' to be done." *Id.* In other words, whatever the word "correlate" stands for on its own, a doctor can infringe Claim 13 only by correlating an *elevated* homocysteine level with a cobalamin or folate deficiency.

2. Induced Infringement. LabCorp also argued (1) that it could not be liable for contributory infringement because there are substantial *non*-infringing uses for single

homocysteine tests—most importantly, to assess for risk of heart disease; and (2) that it could not be liable for induced infringement because respondents presented no evidence that LabCorp specifically intended to induce infringement.

The Federal Circuit did not reach the contributory infringement argument. Instead, it held that LabCorp could be held liable for induced infringement merely because certain educational and informational materials published by LabCorp state the basic medical fact "that elevated total homocysteine correlates to cobalamin/folate deficiency." App. 15a According to the panel, the dissemination of this scientific fact to doctors constituted induced infringement because LabCorp thereby "promoted total homocysteine assays for detecting cobalamin/folate deficiency." *Id.*[5]

3. Invalidity. The panel also rejected LabCorp's related argument that if Claim 13 were to be construed as broadly as respondents contended, it would be invalid. *First*, LabCorp had argued that Claim 13 was "indefinite," and therefore invalid, because nothing in the patent actually informs practitioners how to "correlate," which the District Court had held must entail a "discrete, sequential process step." A221. The panel, however, found that Claim 13 was not indefinite because "the claim construction exercise at the trial court produced a discernible and clear meaning." App. 16a. The

[5] In fact, the panel was incorrect as a factual matter. LabCorp's Directory of Services—described by the panel as "stat[ing] that elevated total homocysteine correlates to cobalamin/folate deficiency"—in fact *expressly* refers physicians to the *panel test* (on which LabCorp continues to pay royalties) to determine folate deficiencies. A8501 (referring to "megaloblastic anemia profile" panel test), A8505 (same), A8499 (panel test). The only other "evidence" of intent the panel identified—two Continuing Medical Education articles—nowhere promote using a total homocysteine test to detect vitamin deficiencies. One discusses the royalty-bearing panel test. *See* A9622. The other simply discusses the significance of homocysteine as a risk factor for *heart disease*. A9610.

panel did not further elaborate on this holding, which presumably referred to its view, expressed earlier in the opinion, that the "correlating" step merely requires a doctor to look at a test result and think about the possible connection to vitamin deficiencies.

Second, LabCorp argued that Claim 13 lacked an adequate "written description." The panel rejected that argument, holding that the record showed "that physicians in homocysteine research * * * understood from the specification that the '658 patent inventors possessed the 'correlating' step at the time they filed the patent application," and that "LabCorp's own expert and employees understood the meaning of 'correlating.' " App. 17a.

Third, LabCorp argued that Claim 13 did not sufficiently "enable" doctors to practice the patented "correlating" step. The panel, however, held that "the correlating step is well within the knowledge of one of skill in this art" because "[t]he correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." App. 18a. In support of this holding, the panel cited statements in the Patent that elevated homocysteine levels "are indicative of cobalamin and/or folate deficiency" in that "the higher the level, the stronger the indication." App. 18a (quoting '658 Patent, col. 9, ll. 26-29).[6]

4. Willfulness, Enhanced Damages, Injunction, and Attorneys' Fees. The panel also affirmed the District Court's award of enhanced damages based on the jury's finding of willful infringement. App. 26a. And it affirmed

[6] LabCorp also argued that Claim 13 was invalid based on "prior art" because it had long been known that elevated levels of homocysteine were connected to conditions such as those described in the Patent. The court rejected these arguments, holding that the prior art did not set forth the *precise* correlation between *total* homocysteine (as opposed to one of its principal components) and cobalamin or folate deficiencies. App. 19a.

the injunction prohibiting LabCorp from directly performing homocysteine tests under any testing method. App. 27a.

Eight months after it entered final judgment on the merits, the District Court also entered an award of more than $1.1 million in attorneys' fees and costs against LabCorp, based on the earlier finding of willful infringement. LabCorp separately appealed that judgment to the Federal Circuit, and that appeal was stayed pending the outcome of the merits appeal.[7]

On August 5, 2004, the Federal Circuit denied LabCorp's timely petition for rehearing or rehearing en banc. App. 40a.

REASONS FOR GRANTING THE WRIT

I. THE COURT SHOULD RESOLVE THE CONFLICT OVER THE REQUIREMENTS FOR INDUCED INFRINGEMENT.

A. The Conflict Is Well-Recognized And Intractable.

A principal controversy underlying this case stems from two inconsistent Federal Circuit opinions issued over a decade ago regarding the requirements for induced infringement under Section 271(b) of the Patent Act: *Manville Sales Corp.* v. *Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990), and *Hewlett-Packard Co.* v. *Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990). Section 271(b) permits a patentee to bring an action against "[w]hoever actively induces" patent infringement. 35 U.S.C. § 271(b). Although this Court has never directly addressed the issue, it is clear that there are at least two prerequisites for inducement to infringement: (1) a showing that the conduct being induced is in fact direct infringement and (2) proof of intent to induce infringement. *See, e.g., Minnesota Min. &*

[7] Concurrently with this petition, LabCorp has filed a motion with the Federal Circuit requesting entry of judgment on that appeal based on the affirmance of the merits appeal, while expressly preserving all of LabCorp's arguments against that affirmance for review by this Court.

Mfg. Co. v. *Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002).

The Federal Circuit, however, is hopelessly divided as to what suffices to meet the intent requirement. Indeed, the Federal Circuit itself has recently recognized the longstanding schism. As the court lamented just weeks ago, "there is a lack of clarity concerning whether the required intent must be merely to induce the specific acts or additionally to cause an infringement." *Insituform Technologies, Inc.* v. *CAT Contracting, Inc.*, — F.3d —, 2004 WL 2240591, at *18 (Fed. Cir. Oct. 4, 2004).[8] The decision below directly implicates this conflict, and holds that the intent requirement can be satisfied merely by the publication of truthful information regarding a basic scientific fact. This Court should grant certiorari to resolve the conflicting standards announced by the Federal Circuit—a conflict that has been percolating for over a decade, that is at the core of the extraordinary holding below, and that the Federal Circuit has shown no ability to resolve on its own.

The conflict is both clear and direct. In *Hewlett-Packard*, 909 F.2d at 1469, the Federal Circuit held that the intent prong of inducement to infringe requires "proof of actual intent to cause the acts which constitute the infringement." According to this standard, a defendant may have the requisite intent by encouraging others to undertake infringing acts, even if the defendant believes that those acts do not constitute patent infringement and the defendant does not literally intend for patent infringement to occur. *See also Moba, B.V.* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1318 (Fed. Cir.), *cert. denied*, 124 S. Ct. 464 (2003). The court below applied the *Hewlett-Packard* standard. *See* App. 14a.

[8] Although the court noted the conflict in *Insituform*, it did not resolve the conflict because it found sufficient evidence under either standard. *Id.*

By contrast, in *Manville Sales*, 917 F.2d at 553, the Federal Circuit held that the intent prong for inducement to infringe requires the plaintiff to show that the alleged inducer "knowingly induced infringement." In other words,

> [i]t must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Id. (emphasis in original).

Thus, under the *Manville Sales* analysis, a party like LabCorp could only be liable for inducement to infringe if it knew or should have known its acts were inducing actual infringement. Simple " 'knowledge of the acts alleged to constitute infringement' is not enough." *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (citation omitted); *see also Ferguson Beauregard/Logic Controls* v. *Mega Sys., LLC*, 350 F.3d 1327, 1342 (Fed. Cir. 2003) (applying *Manville Sales* standard); *Minnesota Mining & Mfg. Co.*, 303 F.3d at 1305 (applying *Manville Sales* standard, but noting *Hewlett-Packard* alternative standard); *Mentor H/S, Inc.* v. *Medical Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001) (applying *Manville Sales* standard).

The conflict also extends beyond patent law. The Federal Circuit has routinely declared that Section 271(b) imposes liability for "aiding and abetting" the commission of a legal wrong. *See, e.g., National Presto Indus., Inc.* v. *West Bend Co.*, 76 F.3d 1185, 1194-96 (Fed. Cir. 1996). Yet in its nonpatent cases, the court has held that liability for aiding and abetting a tort requires proof of a defendant's specific intent to violate the law. *See, e.g., United States* v. *Hitachi America, Ltd.*, 172 F.3d 1319, 1337 (Fed. Cir. 1999) ("legal authority in various civil and criminal contexts supports the view that liability for aiding or abetting requires, *inter alia*,

proof of knowledge of unlawfulness, also articulated as intent to violate the law"). The general aiding and abetting standard applied by the Federal Circuit in non-patent cases is consistent with its approach in *Manville Sales*. By contrast, the *Hewlett-Packard* standard applied in this case—which imposed liability on LabCorp based on the mere dissemination of truthful scientific information—is inconsistent with this general standard.

It is not only the Federal Circuit that has noticed this conflict; commentators have as well. Thus, one commentator has noted that "a clear definition of the mens rea required for inducement liability has eluded even the Federal Circuit." *Recent Cases, "Patent Law—Active Inducement of Infringement,"* 115 Harv. L. Rev. 1246, 1246 (Feb. 2002). And another has stated that the Federal Circuit "has faltered in its attempts to define the level of culpable intent required for a party to be guilty of inducement to infringe. By issuing conflicting decisions on the matter, the Federal Circuit has created a great deal of uncertainty in district courts as to the controlling standard." Michael N. Rader, *Toward A Coherent Law Of Inducement To Infringe: Why The Federal Circuit Should Adopt The* Hewlett-Packard *Standard For Intent Under § 271(b)*, 10 Fed. Circuit B.J. 299, 300 (2000). *See also* Robert O. Bolan & William C. Rooklidge, *Imputing Knowledge To Determine Willful Patent Infringement*, 24 Am. Intell. Prop. L. Ass'n Q.J. 157, 163 n.13 (1996) (intent standard for inducement liability is "totally unclear").

Even though the Federal Circuit's exclusive Patent Act jurisdiction generally precludes Circuit splits in patent cases, this Court has granted certiorari in the past when the Federal Circuit has shown that it cannot resolve an important question of patent law. *See, e.g., Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727 (2002); *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997). The Court should do so here. The conflict within the Federal Circuit has persisted for more than a

decade and the extended division in that court shows that the question has gone as far as it can in that Circuit. The time is thus ripe for this Court to intervene to bring certainty and consistency to the law. And, as next shown, this is the proper case in which to do so.

B. This Case Presents An Appropriate Vehicle For Resolving The Conflict.

This case is an especially appropriate vehicle for clarifying the standard required for induced infringement, given the minimal evidence that the Federal Circuit held constituted the requisite intent to infringe, and the harmful effect of the court's holding on patient care. The Federal Circuit held that LabCorp was guilty of inducement based *solely* on LabCorp's dissemination to doctors of a basic medical fact—that an elevated level of total homocysteine correlates with certain vitamin deficiencies. This evidence clearly would not satisfy the *correct* test for inducement—which should require a showing that a defendant specifically intended to infringe a patent, rather than just evidence that infringement may have been the result of the defendant's actions.

The evidence relied on by the Federal Circuit demonstrates no specific intent by LabCorp to induce any doctor to infringe the '658 patent. According to the Federal Circuit, the sole evidence of LabCorp's intent to induce infringement consisted of Continuing Medical Education articles and a Directory of Services—both general informational resources for doctors—which "state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements." App. 15a. According to the court, "[t]he publications advocate use of the [homocysteine] assay to identify a need for cobalamin/folate supplements." *Id.* Based *only* on this evidence, and nothing else, the Federal Circuit held that "a reasonable jury could find intent to induce infringement because

LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency." *Id.*[9]

This case thus starkly presents the conflict. Applying the flawed *Hewlett-Packard* test, the Federal Circuit held that LabCorp willfully violated the patent laws merely by publishing general informational articles "stat[ing] that elevated total homocysteine correlates to cobalamin/folate deficiency"—in other words, by simply disseminating a basic scientific fact that is helpful to doctors seeking to diagnose and treat their patients. By contrast, decisions applying the *Manville Sales* standard have required much more before intent to induce can be found. Under that standard, recitation of a basic scientific fact cannot be induced infringement unless accompanied by overt guidance, instruction, or encouragement—in other words, proof of *specific intent*—that a patent be infringed.[10] Here, LabCorp has never provided directions or instructions to doctors or anyone else on how to infringe the '658 patent. To the contrary, LabCorp consistently honored its license agreement and paid royalties for

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[9] In fact, as noted above, the Federal Circuit misconstrued the evidence on which it relied. The cited statements referred to the *panel* test, on which LabCorp has always paid royalties, not the single homocysteine test at issue in this case. *See supra* n.5.

[10] *See, e.g., Biotec Biologische Naturverpackungen GmbH & Co. KG* v. *Biocorp, Inc.*, 249 F.3d 1341, 1351 (Fed. Cir. 2001) (defendant induced infringement by specifically instructing customers to process product so as to meet every limitation of patented claim); *Ferguson Beauregard*, 350 F.3d at 1342 (no induced infringement where no evidence that defendant knew or should have known his actions would induce infringement); *Micro Chem., Inc.* v. *Great Plains Chem. Co.*, 194 F.3d 1250, 1261 (Fed. Cir. 1999) (no induced infringement when undisputed facts did not establish the knowledge necessary to find specific intent to induce); 5 Donald S. Chisum, *Chisum on Patents* § 17-04[4][f] at 17-103 (2004) (citing decisions finding inducement where defendants gave "instructions and directions as to the infringing use").

the panel test, which uses the specific assay method covered by the Patent. A7952, A230-31. And LabCorp always understood and believed that the doctors who ordered *single* homocysteine tests were doing so to screen for risk of heart disease, not to diagnose vitamin deficiencies.

The facts of this case thus illustrate the grave dangers for medical testing and treatment of allowing such a relaxed test for inducement. Under the Federal Circuit's holding, any person—such as an author of a medical textbook—would be guilty of induced infringement if he or she simply published the basic scientific fact that elevated levels of homocysteine correlate to deficiencies of cobalamin or folate. For that is the sum total of the evidence which the Federal Circuit held constituted LabCorp's intent to induce—the publication to doctors of this basic medical fact. A truthful statement of medical fact—standing alone—cannot under any circumstances constitute a specific intent to infringe a patent.

To hold otherwise would dramatically transform the patent laws from an engine of discovery into a means of preventing the dissemination of basic scientific information. This Court has long recognized that scientific facts and laws of nature are outside the scope of patentable inventions. *See, e.g.*, *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981) ("[e]xcluded from * * * patent protection are laws of nature, natural phenomena, and abstract ideas"); *Gottschalk* v. *Benson*, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, * * * are not patentable, as they are the basic tools of scientific and technological work."); *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("[P]atents cannot issue for the discovery of the phenomena of nature."); *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). The reason for the rule is that scientific principles and laws of nature—which have existed throughout time—"ought not to be the subject of exclusive rights of any one person." *In re Meyer*, 688 F.2d 789, 795 (C.C.P.A. 1982) (*citing Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156 (1852)).

In this case, the Federal Circuit improperly broadened this limited scope of the patent laws in at least two ways. First, the court incorrectly construed the Patent as conferring a monopoly over the thought processes of doctors, by holding that direct infringement occurs whenever a doctor looks at a homocysteine test result and thinks about a possible connection to vitamin deficiencies—regardless of what testing method is used and without requiring any further confirmation of an actual deficiency. *See supra* at 8-9.[11] But the court took its flawed holding a step further, by holding that a third party such as LabCorp, which indisputably committed no direct infringement, can be held liable for indirect infringement merely by reciting a medical fact. Given that no person can claim a patent over a scientific fact, it must follow that no person can be guilty of induced infringement merely by stating such a fact.

In sum, the Federal Circuit is itself hopelessly divided on these issues and this case presents the proper vehicle to resolve the conflict and restore certainty to the law. The Court should therefore grant certiorari to confirm that a party cannot be liable for patent infringement merely because it has informed doctors of a medical fact.[12]

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[11] The patent specification nowhere discloses that the correlating step can be performed in the physician's mind by merely looking at a homocysteine level test result. The patent teaches, rather, that physicians must perform other tests revealing a symptom of cobalamin or folate deficiency before it can be established that elevated homocysteine has any relationship with, or is caused by, a cobalamin or folate deficiency. A911, col. 5, ll. 40-63. This error, which is related to the Federal Circuit's errors on induced infringement and invalidity, is also presented for this Court's review. *See* S. Ct. R. 14.1(a) (Court will consider all issues "fairly included" in the questions presented).

[12] The errors outlined in this petition directly implicate the jury's findings of willful infringement and breach of contract, and the District Court's awards of enhanced damages and injunctive

II. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISIONS ON CLAIM CONSTRUCTION AND INVALIDITY.

Certiorari is also warranted because the Federal Circuit's decision below conflicts with precedents of this Court, as well as the Federal Circuit's own precedents, on both patent claim construction and invalidity. *See* S. Ct. Rule 10(c). Given the importance of the case, and the clear errors committed by the Federal Circuit, the Court should grant certiorari to resolve these conflicts as well.

A. The Federal Circuit Impermissibly Ignored A Critical Claim Limitation That Was Added To Overcome The Prior Art.

This Court has made clear that the scope of a patent monopoly is strictly limited to the terms of the claim as drafted by the patent holder. As the Court has held, all limitations of a claim must be considered meaningful, and the focus of claim construction must begin with, and remain centered on, the language of the claims themselves.[13] The Federal Circuit

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relief, which all depend at least in part on the findings of infringement and validity. Accordingly, reversal of the Federal Circuit on infringement and validity requires reversal on these issues as well.

[13] *See, e.g., Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 230 (1964) ("Once the patent issues, it is strictly construed" and "it cannot be used to secure any monopoly beyond that contained in the patent"); *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 339-340 (1961) ("the claims made in the patent are the sole measure of the grant"); *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what the words in the claim mean.") (internal citations omitted); *Milcor Steel Co.* v. *George A. Fuller Co.*, 316 U.S. 143, 146 (1942) ("Out of all the possible permutations of elements which can be made from the specifications, [the patentee] reserves

previously has recognized this basic rule. *See, e.g., Texas Instruments, Inc.* v. *ITC*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (courts " 'can neither broaden nor narrow claims to give the patentee something different than what he has set forth.' ") (quotation omitted). Yet in this case the panel majority impermissibly ignored a claim limitation that was added to overcome the prior art (A973, A975) so as to allow a patent to cover the exact opposite of what was claimed. This departure from settled precedent also warrants this Court's review.

The dissent detailed the majority's error, noting that "the majority impermissibly expand[ed] the scope of claim 13 beyond the actual words of the claim." App. 29a. As the dissent carefully details, the majority rewrote the claim for purposes of its infringement analysis so that it covered not just what the claim actually specifies—correlation of "elevated" test results—but also the exact *opposite* of what it specifies—correlation of *un*elevated results, which comprise more than *80%* of all test results. Even after the court accepted the district court's construction that "elevated" means "raised above the normal range," *id.*, and even with claim language requiring one to "correlate[e] an *elevated* level," App. 8a, the majority held that tests revealing *no* elevated level were still infringing. In so holding, "the majority disregard[ed] the explicit limitation * * * that only an 'elevated' level of homocysteine can be 'correlated' with a vitamin deficiency." App. 31a. *See also id.* at 32a (majority "ignores the term 'elevated' ").

As Judge Schall further explained:

> There is no language in Claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency. Ordinary meaning thus

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for himself only those contained in the claims.") (quotation omitted).

> dictates that a patient's homocysteine level be "elevated" in order for a physician to practice claim 13. If the patient's homocysteine levels are not "elevated," by the plain language of the claim, there is no "correlating" to be done.

App. 31a.

That is precisely right. To infringe Claim 13, there must be a vitamin *deficiency*; for there to be a *deficiency*, there must be an "*elevated*" homocysteine level. Indeed, the preamble to the claim describes it as "[a] method for detecting a *deficiency of cobalamin or folate*." App. 3a. This "method" simply has no application where there is an *un*elevated homocysteine level, since such a normal test result can in no way detect a vitamin deficiency. Whatever the term "correlating" may mean by itself, the patent claim expressly covers only the correlation of *elevated* test results.

The majority's holding contravenes this Court's precedents in a striking and dangerous way. For the Federal Circuit has now held that a claim term can include the exact *opposite* of what the claim actually provides. If this holding is not corrected, practitioners will no longer be able to rely on the express claims of a patent. As this Court has held,

> [t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others, and the assurance that the subject of the patent will be dedicated ultimately to the public. The statute seeks to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights.

General Elec. Co. v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938). It is in large part for this reason that courts may

not redraft claims after-the-fact to sweep non-infringing conduct into the realm of infringing conduct.[14]

If not corrected, the Federal Circuit's holding will foster precisely the uncertainty that the patent laws are intended to prevent. The Court should grant certiorari to restore this certainty by confirming that a claim term cannot encompass the opposite of what was actually claimed.

B. A Patent That Simply Claims A Scientific "Correlation"—Without More—Is Indefinite, Insufficiently Described, And Non-Enabling.

The Court should also grant certiorari because the Federal Circuit contravened precedent by holding valid a patent that claims nothing but a scientific correlation. Claim 13 purports to claim a method consisting only of (1) assaying for elevated homocysteine levels, and (2) "correlating" elevated levels with vitamin deficiencies. App. 3a. Neither the claim nor the specification says anything about how one is to conduct the assay—indeed, Claim 13 covers *any* conceivable assay method. And more important, the patent says *nothing at all* about how one is to "correlate" an elevated level with a vitamin deficiency; that task is completely undescribed by the patent. Such a vague claim cannot be valid; for if it could be, parties could claim patent monopolies over basic scientific facts rather than any novel inventions.

To be valid, a patent must point out with particularity, and distinctly claim, the "invention." *See* 35 U.S.C. § 112 ¶ 2 (patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject

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[14] *See, e.g., Quantum Corp.* v. *Rodime, Plc*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("Although we construe claims, if possible, so as to sustain their validity,* * * it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.") (internal citation omitted); *Becton Dickinson & Co.* v. *CR Bard Inc.*, 922 F.2d 792, 799 n.6 (Fed. Cir. 1990) ("Nothing in any precedent permits judicial redrafting of claims.").

matter which the applicant regards as his invention"). An indefinite patent is invalid, and "[t]he definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." *Union Pac. Resources Co.* v. *Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). Similarly, a patent must also contain a sufficient written description and must enable a practitioner to know how to practice it. *See* 35 U.S.C. § 112 ¶ 1 (claim must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same * * *"). These requirements ask whether the patent specification "allow[s] persons of ordinary skill in the art to recognize that the [inventor] invented what was claimed," *Gentry Gallery, Inc.* v. *Berline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998), and "teach[es] those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech Inc.* v. *Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir.) (citation omitted), *cert. denied*, 522 U.S. 963 (1997).

A claim that simply directs a practitioner to "correlate" a test result with a medical condition fails all these tests and is therefore invalid. As the District Court correctly concluded, the "correlating" set forth in Claim 13 must "comprise a discrete, sequential process step." A221. But it has never been clear what the "correlating" step is—beyond a doctor simply thinking about the basic scientific association between elevated homocysteine levels and certain vitamin deficiencies. All the patent tells a prospective practitioner is that a person with an elevated homocysteine level *may* have a vitamin deficiency, which is simply a scientific fact. Such a claim is invalid for indefiniteness because one of ordinary skill in the art cannot determine its scope without specula-

tion.[15] Likewise, because neither the claim nor the specification describe what a practitioner must do to perform the active "correlating" step, it fails the written description and enablement requirements, for no one of skill in the art can tell, without undue experimentation, what the Claim 13 requires be done with the medical fact at issue.[16]

If the Court allows the Federal Circuit opinion to stand, anyone could obtain a patent on any scientific correlation—that there is a link between fact A and fact B—merely by drafting a patent claiming no more than "test for fact A and correlate with fact B," without any explanation of the testing or correlation processes. Claim 13 does no more than that. If the Federal Circuit decision is not corrected, CTI and others like it would improperly gain monopolies over basic scientific facts rather than any novel inventions of their own. As explained above, this Court's precedents are settled that no such claim can be allowed. *See supra* at 18.

As construed by the Federal Circuit, the correlating step does *not* require a doctor to actively perform any discrete

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[15] *See In re Steele*, 305 F.2d 859, 862-863 (C.C.P.A. 1962); *Honeywell Int'l, Inc.* v. *ITC*, 341 F.3d 1332, 1339 (Fed. Cir. 2003) (holding claim indefinite where patent claims and specification did not specify how to measure specific claimed parameter, and known methods produced varying results); *Union Pacific*, 236 F.3d at 692 (finding patent claim invalid for indefiniteness based on its use of the word "comparing").

[16] *See Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991); *Union Pacific*, 236 F.3d at 688, 691 (affirming district court finding of patent invalidity when the patent lacked any explanation about *how* "correlating" was "achieved;" practitioners of the patent were thus left without adequate guidance on how to put the patent's teachings to use); *National Recovery Techs., Inc.* v. *Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196-97 (Fed. Cir. 1999).

step in the patented process. *See* App. 8a (claim "only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies."); App. 12a ("the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms"). But this Court's cases are clear that a method patent requires one to do something with a scientific fact. *See Funk Bros. Seed,* 333 U.S. at 130 ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law to a new and useful end."); *Mackay Radio & Tel.*, 306 U.S. at 94 ("While a scientific truth, or the mathematical expression of it, is not [a] patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").

Here, the patent as construed by the Federal Circuit tells practitioners merely that there is a scientific connection between elevated homocysteine and certain vitamin deficiencies. There is no further instruction as to what a practitioner must do to perform the "correlating" step. Under this Court's precedents, such an undefined claim cannot constitute a valid patented invention.

III. THIS CASE INVOLVES A QUESTION OF NATIONAL IMPORTANCE.

This case involves a question of extraordinary national importance. The Federal Circuit has held that one can gain a valid, legally protected patent monopoly over a basic scientific correlation such that any doctor who looks at test results and uses his or her medical knowledge just to *think* about what the result signifies has infringed the patent unless a license is granted and a royalty paid. And the Court went even further by holding that a third party that committed no direct infringement is nevertheless liable for induced infringement merely because it has disseminated that scientific

fact to doctors who may use it in diagnosing and treating patients. If this decision is allowed to stand, it will have grave adverse consequences for medical treatment throughout the Nation.

The patent laws appropriately protect new methods of testing for medical conditions. Thus, LabCorp has always recognized respondents' patent on the GCMS method for homocysteine tests and has always paid royalties when using that patented method. But what patent law cannot, and should not, protect are the medical facts that a test result may convey. *See supra* at 18. Protecting patented test methods encourages medical breakthroughs. But barring the disclosure of truthful medical knowledge prevents the medical profession from exercising appropriate medical judgment. Medical testing and treatment will be severely harmed if threats of patent lawsuits pressure doctors to delay or refrain from learning about medical facts that could help provide appropriate care and diagnosis.

The Federal Circuit's decision has cast precisely this kind of pall. The court upheld a patent claiming a right to prevent doctors from even *thinking* about a basic medical fact, holding that a doctor's mere speculation about the connection between homocysteine levels and vitamins constitutes the patented "correlating" step of Claim 13. And the court has held LabCorp liable for induced infringement—and enjoined it from directly performing any homocysteine tests under any method—merely because it has published this basic scientific fact. Respondents, moreover, have already shown that they are not stopping at LabCorp in their efforts to deter the performance of homocysteine tests. The very day the Federal Circuit's decision issued, respondent CTI filed a similar lawsuit against the *manufacturer* of a homocysteine test kit, accusing it of inducing infringement by doctors. *See Competitive Techs., Inc.* v. *Abbott Labs, Inc.*, No. 1:2004cv01169 (D. Colo.) (filed June 8, 2004). Two months later, CTI filed a second similar suit. *See Competitive Techs., Inc.* v. *Bayer*

Corp., No. 1:2004cv01712 (D. Colo.) (filed Aug. 17, 2004). And under respondents' and the Federal Circuit's view of the law, thousands of doctors are daily infringing the patent by "correlating" test results in their heads.

Single homocysteine tests are now critical to proper medical care and treatment in large part because of their utility in diagnosing increased risk of heart disease—the Nation's number one health problem. Indeed, the increased demand experienced by LabCorp occurred after the American Heart Association issued guidance to physicians informing them of the importance of homocysteine tests. *See* A8426. CTI itself has stated that "the size of the market could grow to *500 million assays* over the next five years." *See* Homocysteine Assay (http://www.competitivetech.net/technologies.htm#Homo); *see also* A7973-75, A7976-78 (1999 CTI press releases expressly linking elevated levels of homocysteine and heart disease, and noting that the number of tests was approaching approach 100 to 125 million tests per year). Yet according to the Federal Circuit, every doctor who orders one of these tests is infringing the Patent—no matter the method or reason for performing the test—unless CTI is paid a royalty. And unless the test has been licensed, any person who even informs a doctor of the basic scientific fact that elevated homocysteine is connected in some way to cobalamin or folate levels is guilty of induced infringement. Under the Federal Circuit's decision, doctors will now be deterred from treating patients, and other medical professionals will now be deterred from providing critical information needed for patient care.[17]

The importance of this case also extends far beyond the patent at issue. Under the Federal Circuit's holding, anyone

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[17] As noted above, homocysteine tests are useful for more than just screening for risk of heart disease. Elevated homocysteine levels have been associated with numerous other conditions ranging from lupus to Alzheimer's disease. *See supra* at 3.

who claims to be the first to discover a scientific correlation can patent that correlation—and thereby demand a royalty from anyone who even thinks about it—simply by drafting a vague "test plus correlate" claim. And that person could then prevent others from disseminating that patented scientific fact on the theory that such dissemination induces infringement. For example, someone who claims to have discovered the basic correlation between high cholesterol and heart disease risk could patent a two-step method: test for elevated cholesterol and "correlate" with risk of heart disease. The hypothetical patentee then could prevent doctors from ordering any cholesterol tests and prevent anyone else—including professors or authors of medical textbooks—from informing doctors about the basic correlation. Literally *any* scientific "correlation" could be patented in such a matter, thereby employing the patent laws to stifle rather than encourage the dissemination of scientific knowledge.

LabCorp was held liable in this case because it published a medical fact useful in the treatment of patients, and for no other reason. Medical facts, like all scientific principles and laws of nature, belong to the public. Medical professionals and others must be able to discuss such facts—including the correlation at issue here—without fear of liability for infringing or inducing another to infringe a patent. The Federal Circuit's decision in this case thus threatens to hinder the free and open dissemination of critical medical information. Indeed, the American Heart Association presently publishes on its website truthful information about homocysteine and vitamins that is identical in all relevant respects to the statements for which LabCorp was held liable for inducing infringement.[18] Under the Federal Circuit's holding, these

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[18] The American Heart Association's website currently provides the following information:

> Homocysteine is an amino acid in the blood. Too much of it is related to a higher risk of coronary heart disease, stroke and peripheral vascular disease (fatty deposits in peripheral

kinds of statements from medical professionals, and others like them, could well lead to crippling liability.

Although LabCorp is the party that bears the judgment in this case, if the Federal Circuit's decision is not reversed the ultimate losers will be thousands of doctors and millions of their patients. The Court should therefore grant review to clarify that the patent laws do not permit a party to gain a monopoly over the thought processes of doctors or prevent anyone from simply disseminating truthful information about a basic scientific fact critical to patient care.

CONCLUSION

For the foregoing reasons, the petition should be granted and the judgment below reversed.

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arteries). * * * Folic acid and other B vitamins help break down homocysteine in the body. * * * [P]atients at high risk should be strongly advised to be sure to get enough folic acid and vitamins B-6 and B-12 in their diet.

Homocysteine, Folic Acid and Cardiovascular Disease (www.americanheart.org/presenter.jhtml?identifier=4677).

APPENDIX

APPENDIX A

United States Court of Appeals for the Federal Circuit

03-1120

METABOLITE LABORATORIES, INC.
and COMPETITIVE TECHNOLOGIES, INC.,

Plaintiffs-Appellees,

v.

LABORATORY CORPORATION OF AMERICA
HOLDINGS
(doing business as LabCorp),

Defendant-Appellant.

Glenn K. Beaton, Gibson, Dunn & Crutcher LLP, of Denver, Colorado, argued for plaintiffs-appellees. With him on the brief were *J. Gregory Whitehair* and *Amanda J. Tessar*. Also on the brief was *Mark A. Perry*, of Washington, DC.

Jonathan S. Franklin, Hogan & Hartson L.L.P., of Washington, DC, argued for defendant-appellant. With him on the brief was *Catherine E. Stetson*. Of counsel on the brief was *John P. Higgins*, Alston & Bird, LLP, of Charlotte, North Carolina.

Appealed from: United States District Court for the District of Colorado

Senior Judge Zita L. Weinshienk

DECIDED: June 8, 2004

BEFORE RADER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge.

Opinion for the court filed by *Circuit Judge* RADER, dissenting-in-part and concurring-in-part opinion filed by *Circuit Judge* SCHALL. RADER, *Circuit Judge*.

In the United States District Court for the District of Colorado, a jury found that Laboratory Corporation (LabCorp) indirectly infringed Metabolite Laboratories, Inc.'s (Metabolite's) U.S. Patent No. 4,940,658 (the '658 patent). The jury also found that LabCorp partially breached its contract with Metabolite. Based on this verdict, the district court assessed damages of $3,652,724.61 for breach of contract and $1,019,365.01 for indirect infringement. *Metabolite Labs., Inc.* v. *Lab. Corp.*, No. 99-Z-870 (D. Colo. Dec. 3, 2001). After denying LabCorp's motion for judgment as a matter of law (JMOL), the district court doubled the infringement award for willful infringement and issued a permanent injunction. *Metabolite Labs., Inc.* v. *Lab. Corp.*, No. 99-Z-870 (D. Colo. Nov. 19, 2001). Because the record supports the jury's verdicts and the trial court's decisions, this court affirms.

I.

The '658 patent claims methods for detecting cobalamin or folate deficiency. Cobalamin and folate are both B vitamins, commonly known as B_{12} and folic acid, respectively. A deficiency in these vitamins can cause serious illnesses in humans, including vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency.

Because these B vitamins assist in metabolizing the amino acid homocysteine, scientists directly assayed homocysteine to screen for cobalamin and folate deficiency. These direct homocysteine assays were unreliable. Then researchers at University Patents Inc. (UPI) discovered a relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate. The total homocysteine

test, however, could not alone identify which vitamin was deficient. Total homocysteine includes free and protein-complexed homocysteine and also includes homocysteine derivatives homocystine and homocysteine-cysteine.

Originally, doctors could not conveniently treat both deficiencies because while folate was available in tablet form, cobalamin could only be administered by injection. After cobalamin became available in tablet form, however, doctors could simply order a total homocysteine test and, without identifying the deficient vitamin, treat elevated levels of total homocysteine with a tablet containing both cobalamin and folate. The UPI inventors also developed a test to identify the deficient vitamin using methylmalonic acid (the panel test method). The '658 patent claims both the total homocysteine test and the total homocysteine-methylmalonic acid test.

Claim 13 claims the total homocysteine test:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

'658 patent, col. 11, ll. 58-65.

UPI's successor, Competitive Technologies Inc., licensed the patent to Metabolite, which in turn sublicensed the patent to Roche Biomedical Laboratories (now LabCorp). LabCorp, a laboratory testing company, originally performed total homocysteine assays under the sublicense. But in 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories (Abbott test) and discontinued royalty payments to Metabolite for total homocysteine assays.

In response, Metabolite sued LabCorp for infringement. The district court construed the disputed claim terms, and the case proceeded to a jury. The jury found that LabCorp

breached its license agreement with Metabolite, that LabCorp willfully infringed the '658 patent, and that the claims at issue are not invalid. The jury assessed damages against LabCorp of $3,652,724.61 for breach of contract and $1,019,365.01 for infringement. The district court entered judgment against LabCorp and awarded damages as assessed by the jury.

After the trial, the district court denied LabCorp's motion for JMOL on infringement, breach of contract, invalidity, and willful infringement. In light of the finding of willfulness, the district court doubled the jury's infringement award to $2,038,730.02. The district court also permanently enjoined LabCorp from using the homocysteine-only test. LabCorp appeals the district court's claim construction as well as the denial of JMOL.

II.

Claim construction is a matter of law that this court reviews without deference. *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The jury's finding of infringement, however, raises questions of fact, which this court reviews for substantial evidence. *Embrex, Inc.* v. *Serv. Eng'g Corp.*, 216 F.3d 1343, 1348-49 (Fed. Cir. 2000).

This court reviews a denial of JMOL without deference by reapplying the JMOL standard. Thus, this court will affirm a denial of JMOL unless substantial evidence does not support the jury's factual findings or the verdict rests on legal errors. *Waner* v. *Ford Motor Co.*, 331 F.3d 851, 855 (Fed. Cir. 2003).

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, paragraph 1, is a question of fact that this court reviews for substantial evidence. *Union Oil* v. *Atl. Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000). Enablement is a matter of law that this court reviews without deference; however, this court reviews the factual underpinnings of enablement for substantial

evidence. *BJ Servs. Co.* v. *Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1371-72 (Fed. Cir. 2003). Similarly, this court reviews the legal determination of obviousness without deference, but reviews its factual underpinnings for substantial evidence. *Teleflex, Inc.* v. *Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002). This court reviews a legal finding of indefiniteness without deference. *BJ Servs.*, 338 F.3d at 1371-72. Whether a prior art reference anticipates a patent is a factual determination that this court reviews for substantial evidence. *Teleflex*, 299 F.3d at 1323.

Whether infringement was willful is a question of fact that this court reviews for substantial evidence. *Crystal Semiconductor Corp.* v. *TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1346 (Fed. Cir. 2001). This court reviews an award of enhanced damages and grant of a permanent injunction for abuse of discretion. *Odetics, Inc.* v. *Storage Tech. Corp.*, 185 F.3d 1259, 1272 (Fed. Cir. 1999).

III.

Infringement

The primary challenge to the jury's indirect infringement verdict requires this court to review the district court's construction of the claim term "correlating." The infringement inquiry is a two-step process. This court construes the disputed claim terms and then compares the properly construed claims to the accused device. *Cybor Corp.*, 138 F.3d at 1454. Thus, this court first reviews the district court's claim construction.

As always, the claim language itself governs its meaning. *Vitronics Corp.* v. *Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). This court construes the meaning of claim language according to its usage and context. *ResQNet.com, Inc.* v. *Lansa, Inc.*, 346 F.3d 1374, 1378 (Fed. Cir. 2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of invention. *See Rexnord Corp.* v. *Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir.

2001). Indeed, normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. *CCS Fitness, Inc.* v. *Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citing *Johnson Worldwide Assocs., Inc.* v. *Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)). Thus, this court sets the meaning of claim terms by ascertaining their technological and temporal context.

In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." *Boehringer Ingelheim Vetmedica, Inc.* v. *Schering-Plough Corp.*, 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing *Teleflex*, 299 F.3d at 1325-26). In other words, a patent applicant may define a term differently from its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. *Id.* Therefore, the primary aids to supply the context for interpretation of disputed claim terms are in the intrinsic record. *Vitronics*, 90 F.3d at 1582 (Fed. Cir. 1996).

Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term. *Middleton, Inc.* v. *Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002) (a patent applicant may "clearly and unambiguously" disavow claim scope during prosecution).

This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. *Pitney Bowes, Inc.* v. *Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999) ("[C]onsultation of extrinsic evidence is particularly appropriate to ensure that [the court's]

understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art."); *Vitronics*, 90 F.3d at 1585. Another excellent source of context for disputed terms is dictionary definitions and treatises. *See, e.g., Tex. Digital Sys., Inc.* v. *Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("[D]ictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.").

As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. *Moba* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1315 (Fed. Cir. 2003) ("Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); *Ferguson Beauregard* v. *Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003) ("The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art."); *Interactive Gift Express, Inc.* v. *Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001) ("[I]t is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art."); *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc) ("[T]he focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). In this case, as evidenced by the jury instruction, the parties agreed that the level of ordinary skill in this field of invention was "a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases."

The disputed term "correlating" appears in the second step of claim 13, which states: "[C]orrelating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." In its *Markman* brief below, LabCorp

urged the district court to construe "correlate" according to its dictionary definition as a verb meaning "to establish a mutual or reciprocal relation of" an elevated level of homocysteine. LabCorp further argued that the district court should construe the "correlating" step as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropyschiatric abnormality," or "[a] deficiency of folate which causes a hematologic abnormality." The district court adopted LabCorp's dictionary definition by construing "correlating" to mean "to establish a mutual or reciprocal relationship between," but declined to "include a reference to hematologic or neuropsychiatric abnormality" in order to avoid impermissibly importing a limitation from the specification.

On appeal, LabCorp argues that claim 13's correlating step should be construed as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality," or a "deficiency of folate which causes a hematologic abnormality." LabCorp interprets the specification to clearly define a "deficiency of cobalamin" as the presence of a clinical or hematologic syndrome or both that responds to cyano-cobalamin treatment, and to acknowledge that some clinical or hematologic syndrome or neuropsychiatric abnormality must be present. Thus, LabCorp contends that the correlation step of claim 13 should be construed to require a showing of a separate hematologic or neuropsychiatric symptom to confirm the "correlation."

The claim states that the method must correlate "an elevated level of total homocysteine . . . with a deficiency of cobalamin or folate." This language does not require a further association between the level of total homocysteine and either a hematologic or neuropyschiatric abnormality or both. The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies. The

claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship.

The preamble further supports the district court's reading of the claim: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals." This language restates that the invention detects vitamin deficiency. This introductory language does not relate those deficiencies to any particular abnormality. A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history. *Catalina Mktg. Int'l, Inc.* v. *Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) (in rare circumstances, a preamble's recitation of intended use may serve to distinguish the prior art).

An examination of the prosecution history of this patent brings the meaning of the preamble into focus. As originally filed, claim 13 did not contain the "correlating" step. The examiner rejected claim 13 under 35 U.S.C. § 112 because it did not "recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample with, etc. The final step should be clearly related to the preamble of the claim." Rather than add a second step as the examiner suggested, however, the applicant responded: "[A]s applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." After this response, the examiner dropped the § 112 objection, but rejected claim 13 under § 102: "In the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention. The claim lacks a positive limitation for correlating to a particular condition and has only one method step recited." At that point, the applicant added the recommended "correlating" step. The examiner then allowed claim 13.

This prosecution history ties the preamble directly to the "correlating" step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency. "Detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. For example, the results of a pregnancy test can either be positive or negative. Either result is informative to the patient. Similarly, in this case, the assaying step can identify an elevated or an unelevated level of total homocysteine. Then the "correlating" step can identify, in cases of elevated levels, a relationship or not to vitamin deficiency. The results in either the assaying or correlating steps are informative. Thus, the preamble supports the district court's construction that "correlating" includes ascertaining either a mutual or reciprocal relationship between total homocysteine and a vitamin deficiency. The preamble does not require this invention to show a further association with an abnormality.

The specification confirms that the claim language does not require as part of the method a confirmation that the elevated level causes some deleterious symptoms or abnormalities. LabCorp points to portions of the specification that discuss the relationship between the elevated levels and either clinical or hematologic symptoms. *See, e.g.*, '658 patent, col. 10, ll. 56-61; col. 12, ll. 8-15. LabCorp would expand those references to require some confirmatory step in the claim. The specification, however, does not require such a confirmatory step. Rather, the specification at one juncture acknowledges that the method can show vitamin deficiency without any clinical symptoms: "These findings led us to conclude that large numbers of patients with cobalamin deficiency lack the 'typical' clinical and hematologic features usually expected to be present in cobalamin deficiency . . . ." *Id.* at col. 11, ll. 40-45. In other words, the specification shows that the method can show an association between elevated levels and vitamin deficiency without any further clinical symptoms. Thus, the district court properly refused

to import into the claims LabCorp's proposed limitation from the specification. The specification itself does not support such a limitation on the meaning of the claims.

As noted earlier, the district court construed "correlating" to mean a "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies. The inventors discovered that assaying total homocysteine correlated with (or predicted relatively accurately) whether a patient had a deficiency of cobalamin or folate. *Id.* at col. 4. ll. 17-23; col. 10, ll. 35-42. The specification explains that an elevated level of total homocysteine often indicates a deficiency, while a non-elevated level indicates no deficiency. For example, the overview of the invention notes: "This invention pertains to . . . methods for determining whether said warm-blooded animal has a cobalamin deficiency, a folic acid deficiency, *neither*, or both." *Id.* at col. 1, ll. 13-15 (emphasis added). Next, in the summary of the invention, the patentee stated: "Accordingly, assays for homocysteine can be used to determine the *presence or absence* of cobalamin and/or folic acid deficiency in warm-blooded animals." *Id.* at col. 5, l. 66 - col. 6, l. 1 (emphasis added). This court observes that the perfect symmetry between "mutual or reciprocal" and "presence or absence" shows that the district court correctly placed the term "correlating" in its proper context with its proper meaning.

Finally, the patentee explained:

> Once folate and/or cobalamin deficiency has been determined, the progress of treatment can be monitored by repeating the assays periodically during and after treatment. A drop in the level of homocysteine in the serum and/or urine after oral or parenteral adminstration of cobalamin and/or folate as the case may be confirms the diagnosis.

Id. at col. 10, ll. 18-24. This recitation confirms that the patentee anticipated assays without an elevated level of total homocysteine, i.e., the reciprocal relationship, would further

confirm the diagnosis by showing an improvement trend after a physician prescribed treatment.

Taken in the context of the entire specification, "correlating" means relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither. In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship). The claim, in other words, provides that if the assay discloses "an elevated level of total homocysteine," the physician determines whether there is a cobalamin or folate deficiency by "correlating," i.e., comparing the elevated level with the normal homocysteine level. In sum, the specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency. Further, the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms. The district court correctly construed the claim.

LabCorp also raises claim construction arguments in its challenge to the trial court's assessment of damages. Specifically, LabCorp contends that only twenty percent of the assays have elevated levels of homocysteine and therefore only this percentage could form the basis for a damages award. As noted earlier, LabCorp itself urged the district court to define "correlating" to include either a mutual or a reciprocal relationship. In the damages calculation, however, LabCorp prefers to restrict the claim to correlations that yield mutual relationships while excluding any reciprocal relationships. This court declines the

invitation to apply a different claim construction for computation of damages than for infringement liability.

As explained above, the mutual relationship is established when an elevated homocysteine level is present, whereas a reciprocal relationship is established when an elevated homocysteine level is absent. LabCorp's new damages argument, in essence, attempts to change its claim construction position to read out the reciprocal relationship that it initially urged. This court, as it does now, has previously declined such invitations. Interactive Gift Express, 256 F.3d at 1346 (Fed. Cir. 2001) ("[A] party will be judicially estopped from asserting a position on appeal that is inconsistent with a position it advocated at trial and persuaded the trial court to adopt."). For all purposes in this litigation, this court affirms the district court's construction of the "correlating" step.

Direct Infringement

The jury found LabCorp liable for indirect infringement. The record must show the presence of direct infringement, however, to support the verdict of indirect infringement. *Joy Techs., Inc.* v. *Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement."). Thus, this court must examine whether there is substantial evidence in the record of the physicians' direct infringement. In that respect, the parties hinge the direct infringement issue solely on whether the physicians perform the correlating step.[1] Hence, we review the record for substantial evidence of that step.

Substantial evidence supports the jury's verdict. The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing. LabCorp's Discipline Director, Dr. Peter Wentz, testified that the physicians receiving total homocysteine assays from

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[1] This court, therefore, does not address the assaying step.

LabCorp carry out the correlating step.[2] Specifically, Dr. Wentz testified that "the correlating step . . . [is] a separate, distinct step that's performed by the physician who receives . . . our results." Inventor Dr. Sally Stabler also testified that it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency.

To support the verdict, the record does not need to contain direct evidence that every physician performed the "correlating" step. "It is hornbook law that direct evidence of a fact is not necessary. 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *Moleculon Research Corp.* v. *CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (citing *Michalic* v. *Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960)). As discussed above, the record contains sufficient circumstantial evidence to permit the jury to imply that physicians directly infringe.

Active Inducement

Section 271(b) of title 35 provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b) (2000). Although not express in the statute, this section requires proof of intent to induce infringement. *See, e.g., Hewlett Packard Co.* v. *Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement"). A patentee may prove such intent through circumstantial evidence, much like direct infringement as discussed above. *See Water Techs.* v. *Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (noting that "circumstantial evidence may suffice" in proving intent).

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[2] Peter Wentz has a doctoral, not a medical, degree.

The record contains such evidence of intent. LabCorp's own publications supply much of this evidence. LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.

Faced with these statements, LabCorp attempts to explain that these articles focus on heart disease rather than vitamin deficiency. As noted earlier, the patent does not require a correlation to some particular medical condition, but to a vitamin deficiency. The publications advocate use of the assay to identify a need for cobalamin/folate supplements. Thus, the vitamin deficiency remains the focus of the assay and the treatment (i.e., vitamin supplements).

Accordingly, a reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency. Moreover, the publications recommend treatment of this deficiency with vitamin supplements. Because "[i]ntent is a factual determination particularly within the province of the trier of fact," *Allen Organ Co.* v. *Kimball Int'l, Inc.*, 839 F.2d 1556, 1557 (Fed. Cir. 1988), this court sees no reason to disturb the jury's finding regarding LabCorp's intent. Therefore, this court affirms the finding of indirect infringement based on the inducement analysis. This court declines to consider contributory infringement.

Invalidity

A patent issued from the United States Patent and Trademark Office (PTO) bears the presumption of validity under 35 U.S.C. § 282. An accused infringer, therefore, must prove patent invalidity under the clear and convincing evidentiary standard. *Advanced Display Sys., Inc.* v. *Kent State*

Univ., 212 F.3d 1272 (Fed. Cir. 2000). LabCorp argues that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness. Likewise, LabCorp contends that claim 18, directed to the panel test, is also invalid on grounds of indefiniteness, and lack of written description and enablement.

Claim 13

First, LabCorp contends that the "correlating" step in claim 13 is indefinite. 35 U.S.C. § 112, second paragraph, provides: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2000). The requirement to "distinctly" claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. *Union Pac. Res. Co.* v. *Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001); *Rosemount, Inc.* v. *Beckman Instruments, Inc.*, 727 F.2d 1540, 1547 (Fed. Cir. 1984). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Exxon Research & Eng'g Co.* v. *United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In this case, as already noted, the claim construction exercise at the trial court produced a discernible and clear meaning. No "material ambiguities" cloud the meaning of "correlating" to the extent that one of skill in the art would find the claim wholly indefinite. *All Dental Prodx, LLC* v. *Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 (Fed. Cir. 2002) ("Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness."). This court affirms the trial court's denial of JMOL on this ground.

LabCorp next argues that the specification does not adequately describe the claimed invention under 35 U.S.C. § 112, first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112, ¶ 1. This language contains both the written description and enablement tests for sufficiency of the specification's disclosure.

With regard to the written description test, this court has previously explained, "the test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." *Moba*, 325 F.3d at 1320 (citing *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). As in the claim construction section above, this court assesses the written description possession test "from the viewpoint of one of skill in the art." *Moba*, 325 F.3d at 1321. The record is replete with evidentiary support that physicians in homocysteine research, i.e., persons of ordinary skill in the art, understood from the specification that the '658 patent inventors possessed the "correlating" step at the time they filed the patent application. For example, the examiner suggested the word "correlating" to the '658 patentee, showing that the PTO read the specification to include that feature. Additionally, the record reflects that LabCorp's own expert and employees understood the meaning of "correlating." Accordingly, this court finds that substantial evidence supports the jury finding that claim 13 was adequately supported by the '658 patent's written description.

The specification also shows that the patentee enabled the claimed invention. In *Union Pacific*, this court held that a claim was not enabled because it did not disclose use of a "comparing" step. 236 F.3d at 691. However, in *Union Pacific*, the inventors "purposely excluded computer programming details" necessary to perform the "comparing"

step. *Id.* at 690. In this case, the correlating step does not require computer technology or extensive computations. Instead, the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art. The correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step. The patentee did not conceal or fail to disclose this correlation, but instead featured it as the centerpiece of the invention. *See, e.g.*, '658 patent, col. 4, ll. 17-20 ("It has now been discovered that an elevated level of total homocysteine in tissues of warmblooded [sic] animals correlates both with cobalamin deficiency and with folic acid deficiency . . . ."); *id.* at col. 5, ll. 64-66 ("It has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue."); *id.* at col. 9, ll. 26-29 ("Homocysteine levels above these [previously specified] ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication.").

The prior art reference (Refsum) does not anticipate claim 13 under 35 U.S.C. § 102. "A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim." *EMI Group N. Am., Inc.* v. *Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001) (citation omitted). At the outset, the Refsum article does not recite all of the claim 13 limitations. Thus, anticipation would have to rely on an inherent disclosure of undisclosed features, in this case, the "correlating" limitation.

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Continental Can Co. v. *Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Refsum does disclose that total homocysteine should be used to investigate "perturbations of homocysteine metabolism in humans during disease or pharmacological interventions that affect metabolism of one-carbon compounds." Refsum, however, does not specifically mention cobalamin or folate deficiencies. Indeed, one of the '658 patent inventors, Dr. Stabler, testified that cobalamin and folate deficiencies constitute just such a perturbation that Refsum suggested warranted further investigation. Rather than necessarily containing the correlation between homocysteine and cobalamin or folate deficiencies, Refsum simply invites further experimentation to find such associations. An invitation to investigate is not an inherent disclosure. Construed most favorably for LabCorp, Refsum discloses no more than a broad genus of potential applications of its discoveries. A prior art reference that discloses a genus still does not inherently disclose all species within that broad category. *See Corning Glass Works* v. *Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989) ("Under [defendant's] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless . . . .").

Moreover, the PTO considered Refsum in allowing the claims. The '658 patent itself discusses Refsum at length at column 6, lines 26-43 and the patent's second page cites Refsum as a reference. Where, as here, the PTO previously considered the prior art reference, LabCorp bears an even heavier burden to prove invalidity. *Hewlett-Packard*, 909 F.2d at 1467. ("This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." (citation omitted)). Accordingly, substantial evidence supports the jury's finding that Refsum does not anticipate claim 13 by inherency.

The test of obviousness in 35 U.S.C. § 103 is the primary condition of patentability. Obviousness hinges on four factual findings: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." *Nat'l Steel Car, Ltd.*, v. *Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 (Fed. Cir. 2004). LabCorp posits that claim 13 is obvious in view of the Refsum article when combined with other references disclosing that partial homocysteine assays could help diagnose cobalamin or folate deficiency. First, as noted above in the anticipation analysis, the examiner considered the Refsum article and also considered all but one of the secondary references that LabCorp contends render the invention obvious in combination with Refsum. The one reference that the examiner did not consider is cumulative of the others. Thus, the heavy burden of proof in the anticipation case also applies to obviousness. *Hewlett-Packard*, 909 F.2d at 1467. Next, the secondary references do not refer to total homocysteine, but rather to homocystine, one of the four components of total homocysteine. Thus, these secondary references do not add considerably to the Refsum disclosure. Finally, even if the secondary references disclosed total homocysteine, the record does not contain evidence showing that one of skill in the art would have been motivated to combine the various references. *Ecolochem, Inc.* v. *S. Cal. Edison Co.*, 227 F.3d 1361, 1372 (Fed. Cir. 2000) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." (quoting *ACS Hosp. Sys., Inc.* v. *Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1984))). These points alone would suffice to support the jury verdict.

Beyond these points, however, the record contains evidence of objective indicia that support the jury's nonobviousness verdict. The record, for example, shows that skilled artisans were initially skeptical about the invention.

See Hughes Tool Co. v. *Dresser Indus., Inc.*, 816 F.2d 1549, 1556 (Fed. Cir. 1987) (initial skepticism of experts is relevant to nonobviousness). The record also shows that Metabolite has licensed the invention to eight companies. *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (extensive licensing supports nonobviousness). Substantial evidence, therefore, supports the implied jury factual findings that support its legal conclusion that claim 13 is not obvious in light of the Refsum article and the cited secondary references.

In sum, this court rejects LabCorp's various attempts to invalidate claim 13. Accordingly, this court affirms the district court's denial of LabCorp's JMOL.

Claim 18

Unlike claim 13, which Metabolite specifically asserted in its motion for partial summary judgment, Metabolite also requested the district court to declare that claim 18 covers the panel test method. Specifically, Metabolite sought a declaration that LabCorp's panel test that determines which particular vitamin is deficient infringes claim 18. The district court granted Metabolite's motion for partial summary judgment, finding that "[c]laim 18 covers LabCorp's performance of the panel test." In turn, LabCorp challenged the validity of claim 18 at trial. Neither party disputes that LabCorp continues to pay royalties for the panel test that provides the capability to identify which of the two vitamins is deficient.

Before this court can reach the merits of LabCorp's validity challenge, however, it must first ascertain whether it has jurisdiction to consider this challenge. Subject matter jurisdiction is an inquiry that this court must raise *sua sponte*, even where, as here, neither party has raised this issue. *Textile Prods., Inc.*, v. *Mead Corp.*, 134 F.3d 1481, 1485 (Fed. Cir. 1998) ("Every federal appellate court has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review,' even though the

parties are prepared to concede it." (quotation omitted)); *see also Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed. Cir. 2004) ("Any party or this court *sua sponte* may raise the question of subject matter jurisdiction.").

Although not as common as the scenario in which the alleged infringer seeks declaratory judgment against the patentee, it is possible for a patentee to also seek a declaratory judgment against a future infringer. *See Lang* v. *Pac. Marine & Supply Co., LTD.*, 895 F.2d 761, 763 (Fed. Cir. 1990) (noting that patentees seeking declaratory judgments against future infringers are rare, yet permissible). In order to demonstrate that an actual case or controversy exists, however, a patentee must demonstrate two elements. First, the patentee must show that the future infringer is "engaged in an activity directed to making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a)." *Lang*, 895 F.2d at 764. The patentee must then demonstrate that the defendant's acts represent a refusal to alter its course of action in light of the patentee's warning actions. *Id.*

The facts of this case, however, demonstrate that there is no real case or controversy regarding the LabCorp panel test, alleged to infringe claim 18. Neither party disputes that the license is still in effect as to the panel tests that LabCorp performs. This license is, in essence, a licensor's covenant not to sue the licensee. *Hilgraeve Corp.* v. *Symantec Corp.*, 265 F.3d 1336, 1346 (Fed. Cir. 2001) (citation omitted). In turn, this court has held that a covenant not to sue deprives a court of declaratory judgment jurisdiction. *Amana Refrigeration, Inc.* v. *Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (citing *Super Sack Mfg. Corp.* v. *Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995)). Accordingly, a licensor who has implicitly covenanted not to sue a licensee by virtue of the license agreement itself cannot seek a declaratory judgment of infringement. Moreover, in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for which it

continues to pay royalties. *Cf. Gen-Probe Inc.*, 359 F.3d at 1382 (holding that a licensee who continued paying royalties to the licensor did not have sufficient apprehension of suit giving rise to declaratory judgment subject matter jurisdiction). The district court's opinion concerning the panel test's infringement of claim 18 was merely advisory. Accordingly, the district court lacked subject matter jurisdiction, and this court vacates that portion of the district court's judgment.

Breach of contract

The interpretation of a contract is a matter of state law. *Power Lift, Inc.* v. *Weatherford Nipple-Up Sys., Inc.*, 871 F.2d 1082, 1085 (Fed. Cir. 1989). A license agreement is at its core a contract. In this case, both parties agree that New Jersey law governs their rights and obligations under the license, including the termination clause. Under New Jersey law, breach of contract is a question of fact properly reserved for a jury. *Magnet Res., Inc.* v. *Summit MRI, Inc.*, 723 A.2d 976, 982 (N.J. Super. Ct. App. 1998). Thus, the standard of review for this court is whether substantial evidence supports the jury's finding.

The jury found that "LabCorp breached the license agreement by terminating it" for the Abbott test. LabCorp contends that it did not formally terminate the contract, because the contract requires that the licensee provide written notice. The record contains no evidence of a written termination. The record does show, however, that LabCorp stopped paying royalties on the total homocysteine tests. Refusal to pay royalties is a material breach of the license. *See Dow Chem. Co.* v. *United States*, 226 F.3d 1334, 1346 (Fed. Cir. 2000). A material breach, in turn, constitutes termination even where the license agreement termination clause does not expressly so provide. *See Apex Pool Equip. Corp.* v. *Lee*, 419 F.2d 556, 562 (2d Cir. 1969) (holding that a licensee's material breach implicitly gives rise to a licensor's right to terminate); *see also Ross-Simons of Warwick, Inc.* v. *Baccarat, Inc.*, 217 F.3d 8, 10 (1st Cir.

2000) ("Every contract involves a bargained-for exchange of obligations, the material breach of which by one party gives the other party a right to terminate."); Restatement (Second) of Contracts § 237 (1981). This court, therefore, affirms the jury's finding that LabCorp breached the license agreement.

Enhanced damages

LabCorp does not directly challenge the jury's willfulness finding. Instead, LabCorp contends that the district court did not discuss the *Read* factors for enhanced damages. *See Read Corp.* v. *Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992), *abrogated in part on other grounds*, *Markman*, 52 F.3d at 975. This court, therefore, addresses only the district court's grant of enhanced damages.

To be sure, this court has enunciated its strong preference that a district court set forth its rationale for an award of enhanced damages to facilitate appellate review. *Read*, 970 F.2d at 828 ("To enable appellate review, a district court is obligated to explain the basis for the award, particularly where the maximum amount is imposed."). On the other hand, this court has also recognized the competing public policy of conserving judicial resources and has cautioned that a remand is a "step not taken lightly." *Consol. Aluminum Corp.* v. *Foseco Int'l Ltd.*, 910 F.2d 804, 814 (Fed. Cir. 1990) (holding that a remand "should be limited to cases in which further action must be taken by the district court or in which the appellate court has no way open to it to affirm or reverse the district court's action under review"). As this court found in *Consolidated Aluminum*, "an appellate court need not close its eyes to the record where, as in this case, there is a way clearly open to affirm the district court's action." *Id.* at 814. Accordingly, this court considers the findings in the record for an abuse of discretion in doubling the infringement damages.

First, this court considers the second *Read* factor, namely whether LabCorp conducted an investigation regarding the scope of the '658 patent in order to form a good-faith belief.

Read Corp., 970 F.2d at 827. LabCorp concedes that Dr. Wentz alone determined that the Abbott total homocysteine tests did not infringe the '658 patent and therefore LabCorp would not need to continue paying royalties to Metabolite. Dr. Wentz himself testified during trial that his determination that the '658 patent did not extend to the Abbott total homocysteine tests was based solely on his interpretation of the license agreement between LabCorp and Metabolite. Moreover, Dr. Wentz testified that he did not consult the '658 patent itself. He also conceded his lack of training in patent law. Based on this evidence alone, the district court could easily have determined that LabCorp did not conduct a reasonable investigation into potential infringement by the Abbott total homocysteine tests. *See Underwater Devices Inc.* v. *Morrison-Knudsen Co., Inc.*, 717 F.2d 1380, 1390 (Fed. Cir. 1983) (affirming district court's grant of enhanced damages where defendant obtained incompetent opinion from in-house counsel who was not a patent attorney, did not consult the patent file histories, and prepared a memo containing "only bald, conclusory and unsupported remarks regarding validity and infringement of the [] patents").

LabCorp's failure to conduct a reasonable and independent investigation regarding the Abbott total homocysteine test is further highlighted by the very terms of the license agreement between LabCorp and Abbott Labs. In the license agreement, Abbott Labs specifically excludes the '658 patent from a warranty covered by an indemnity provision. The warranty specifically excludes:

> [A]ny claim of infringement which may arise under the subject matter of U.S. Patent 4,940,658 and any U.S. or foreign patents claiming priority therefrom or otherwise related thereto. *Except with respect to the foregoing* and at the time of signing this Agreement, Abbott has no reasonable knowledge of any infringement of third party patent rights that would arise from the use of the Imx Homocysteine Research Assay.

(emphasis added). By accepting this provision, LabCorp knew or should have known that Abbott Labs believed the use of the Abbott test might infringe the '658 patent. This language in the license agreement would have put a reasonable licensee on notice to conduct its own investigation regarding the '658 patent coverage of the Abbott total homocysteine test.

In addition to the second *Read* factor, the record also reflects that LabCorp is a large company with extensive financial means, i.e., *Read* factor four. LabCorp's infringing activities of claim 13 began in 1998 without any attempts to remedy the infringement, *Read* factors six and seven, respectively. The district court therefore had evidence before it warranting consideration of at least four *Read* factors.

That the district court did not explicitly set forth its rationale for awarding Metabolite enhanced damages based on LabCorp's willful indirect infringement is not fatal to its decision. As in *Consolidated Aluminum*, "[n]o useful purpose would be served by a remand to enable the district court to tell [this court] in express terms what [it] already know[s] from the record." 910 F.2d at 815. On the basis of the appellate record, this court can readily discern at least four *Read* factors that the district court likely considered when using its discretion to double the infringement damages. Accordingly, this court holds that the district court did not abuse its discretion in enhancing the infringement damages. The district court's failure to discuss the *Read* factors, although contrary to this court's strong preference for the enumerated bases underlying its decision, in this case was at most harmless error.

Injunction

The district court granted Metabolite's motion "to enjoin LabCorp from performing 'any homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method.'"

LabCorp argues that the injunction is too broad because it extends beyond the scope of the claims. To the contrary, the injunction simply addresses LabCorp's specific acts constituting indirect infringement. LabCorp performs the assays upon request from physicians and in doing so indirectly infringes. The district court correctly enjoined LabCorp from infringement. LabCorp also argues that the injunction is defective in form under the Federal Rules of Civil Procedure, because Rule 65(d) requires that a district court "set forth the reasons" for issuing an injunction. The district court's order states that it "finds no sound reason for denying the injunction." While this statement does not explicitly set forth detailed reasons, the district court properly granted the injunction because LabCorp was found to infringe. *See W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988) ("[A]n injunction should issue once infringement has been established unless there is a sufficient reason for denying it."). The district court's brevity is not reversible error.

CONCLUSION

The district court did not err in denying JMOL, awarding enhanced damages, and granting the permanent injunction.

COSTS

Each party shall bear its own costs.

AFFIRMED

United States Court of Appeals for the Federal Circuit

03-1120

METABOLITE LABORATORIES, INC.
and COMPETITIVE TECHNOLOGIES, INC.,

Plaintiffs-Appellees,

v.

LABORATORY CORPORATION OF AMERICA HOLDINGS
(doing business as LabCorp),

Defendant-Appellant.

SCHALL, *Circuit Judge*, concurring-in-part, dissenting-in-part.

I agree with the majority's conclusions with respect to validity, the absence of a case or controversy regarding infringement of claim 18, breach of contract, enhanced damages, and the district court's injunction. However, I respectfully dissent from the majority's construction of claim 13 of the '658 patent. Because I think claim 13 covers only the correlation of elevated levels of homocysteine, I would remand the case for a recalculation of the damages resulting from indirect infringement.

Claim 13 of the '658 patent is an independent claim for a two-step method:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and

> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Col. 41, ll. 58-65. Proper construction of the terms "correlating" and "elevated" is dispositive of the issue of infringement of claim 13. The district court construed "elevated" to mean "raised above the normal range," and "correlating" as "to establish a mutual or reciprocal relationship between." *Metabolite Labs., Inc.* v. *Lab. Corp. of Am. Holdings*, No. 99-Z-870, slip op. at 2-3 (D. Colo. Nov. 29, 2000) (*Markman Order*). Disagreeing with neither of these constructions, the majority holds that when a patient's homocysteine level is not "elevated," claim 13 may nevertheless be infringed because "correlating" includes establishing both a mutual relationship and a reciprocal relationship. The majority states:

> In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship) . . . . [T]he specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency.

In my view, the majority impermissibly expands the scope of claim 13 beyond the actual words of the claim.

I begin with what I see as the controlling principles of claim construction. When interpreting the claims of a patent, the court should look first to the intrinsic evidence of record: the claim, the specification, and, if in evidence, the prosecution history. *Vitronics Corp.* v. *Conceptronic, Inc.*,

90 F.3d 1576, 1582 (Fed. Cir. 1996). There exists within the intrinsic evidence a "hierarchy of analytical tools." *Digital Biometrics, Inc.* v. *Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). First, the language of the claim should be considered—"[t]he actual words of the claim are the controlling focus." *Id.* The claim language defines the bounds of claim scope. *Bell Communications Research, Inc.* v. *Vitalink Communications Corp.*, 55 F.3d 615, 619-20 (Fed. Cir. 1995). Because the claims define the patentee's right to exclude others, "the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim." *Renishaw plc* v. *Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998).

If the meaning of a claim term is clear on its face, consideration of the remaining intrinsic evidence is restricted to determining if a deviation from the clear language of the claim is specified. *Interactive Gift Express, Inc.* v. *Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). The court may consider the patent specification in construing whether the patentee has intended for the meaning of a claim term to deviate from its ordinary meaning. *Vitronics*, 90 F.3d at 1582. The court may also consider the prosecution history, if it is in the record, for evidence of an intentional deviation from the plain meaning of a claim term. *Id.*

Beginning with the ordinary meaning of the claim terms, I too do not disagree with the district court's construction of the terms "elevated" and "correlating." Nor do I disagree with the majority's conclusion that the claim language does not require a further association between the level of total homocysteine and either a hematologic or neuropsychiatric abnormality or both. I cannot agree with the majority, however, that claim 13 is infringed when the test demonstrates that a patient's homocysteine level is *not* "elevated." The plain language of the claim requires "elevated" levels of homocysteine, and a heavy presumption weighs in favor of the ordinary and customary meaning of

that term. *CCS Fitness* v. *Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). As the district court properly construed the term, "elevated" requires a level of homocysteine that is "raised above the normal range." *Markman Order*, slip op. at 2-3. Thus, for claim 13 to be infringed, the homocysteine assay must evince a level of homocysteine that is raised above the normal range. In short, in my view the majority disregards the explicit limitation in claim 13 that only an "elevated" level of homocysteine can be "correlated" with a vitamin deficiency.

There is no language in claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency. Ordinary meaning thus dictates that a patient's homocysteine level be "elevated" in order for a physician to practice claim 13. If the patient's homocysteine levels are not "elevated," by the plain language of the claim, there is no "correlating" to be done. The language of claim 13 does not suggest that the claim encompasses the correlation of unelevated levels with the absence of a deficiency, for the introductory phrase claims "a method for detecting a deficiency," without addressing at all the detection of the absence of a deficiency. '658 patent, col. 41, ll. 58-59.

We have repeatedly stated that "[c]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." *Tex. Instruments Inc.* v. *Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (quoting *Autogiro Co.* v. *United States*, 384 F.2d 391, 396 (Ct. Cl. 1967)); *Oak Tech., Inc.* v. *Int'l Trade Comm'n*, 248 F.3d 1316, 1329 (Fed. Cir. 2001). In this case, however, the majority has permitted claim 13 to be infringed even when homocysteine assays result in unelevated levels. The majority thereby broadens claim 13 to also include, although it is not expressly claimed, correlating unelevated levels of homocysteine with the absence of a vitamin deficiency.

Relying on language from the specification and the prosecution history, the majority brings assays that demonstrate unelevated levels of homocysteine within the province of claim 13 by focusing its construction on the term "correlating." The problem I have with this approach is that it ignores the term "elevated." In addition, because the term "elevated" in claim 13 is unambiguous on its face, the specification and prosecution history of the '658 patent may be consulted only to determine if the patentee intended to deviate from ordinary meaning. *Interactive Gift Express*, 256 F.3d at 1331. There is no evidence before us that any deviation was intended. Throughout the specification, the term "elevated" is consistently used to refer to levels that are raised above average. For example, the specification explains that

> The normal range for homocysteine in human serum is from about 7 to about 22 μmol/liter. *Homocysteine levels above these ranges* are indicative of cobalamin and/or folate deficiency . . . .
>
> * * * *
>
> When homocysteine levels are *elevated* in individuals without inherited defects, at least one of folate or cobalamin is deficient.

'658 patent, col. 9, ll. 23-29, 38-40 (emphases added). Nor is there any evidence from the prosecution history that the patentee relinquished this claim construction in an amendment or in an argument to overcome or distinguish a prior art reference. *Vitronics*, 90 F.3d at 1582. Accordingly, I construe Claim 13 to require an assay that demonstrates an "elevated" homocysteine level, or one "raised above the normal range," in order for the claim to be practiced.

Pursuant to this claim construction, claim 13 is only infringed when the assays performed by LabCorp reveal elevated levels of homocysteine. As LabCorp explains, and as Metabolite does not dispute, approximately eighty to eighty-four percent of the assays LabCorp processes reveal

unelevated levels of homocysteine. I would therefore vacate the jury's verdict that the assays resulting in unelevated levels of homocysteine infringed claim 13, and further vacate and remand the jury's verdict on damages for recalculation based only on those infringing assays that demonstrate elevated levels of homocysteine.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Senior Judge Zita L. Weinshienk

Civil Action No. 99-Z-870

METABOLITE LABORATORIES, INC.,
a Colorado corporation,
and
COMPETITIVE TECHNOLOGIES, INC.,
a Delaware corporation,
Plaintiffs-Appellees,

v.

LABORATORY CORPORATION OF AMERICA HOLDINGS
(doing business as LABCORP),
a Delaware Corporation,
Defendant-Appellant.

ORDER

This suit for patent infringement and breach of contract came before the Court for an eleven-day trial to a jury from November 5 to 20, 2001. The jury awarded Plaintiff Metabolite Laboratories, Inc. (Metabolite) $3,652,724.61 for breach of contract. The jury awarded Plaintiff Competitive Technologies, Inc. (CTI) $1,019,365.01 after finding that Defendant Laboratory Corporation of America (LabCorp) induced patent infringement and contributed to patent infringement. The parties have timely filed eleven post-trial motions.

First, Defendant moves for judgment as a matter of law, or alternatively for a new trial. The Court, however, determines

that there was substantial evidence supporting the jury's verdict, and will not reconsider LabCorp's arguments. Similarly, LabCorp's Motion To Take Judicial Notice will be denied. Defendant also filed a Motion To Alter Or Amend Judgment, to reflect LabCorp's affirmative defense and counterclaim of patent misuse. The issue was reserved by the Court at the time of trial. The Court, however, finds no basis for patent misuse.

Additionally, Plaintiffs have moved for enhanced damages and attorney fees for willful infringement. Upon a finding of infringement, where warranted, a court may increase the damages in an amount up to three times that found or assessed.[1] The jury in this case found that LabCorp willfully infringed claim 13 of the '658 patent. Upon a jury's finding of willfulness, this court must award enhanced damages or provide reasons for not doing so.[2] "The paramount determination in deciding to grant enhancement and the amount thereof is the egregiousness of the defendant's conduct based on all the facts and circumstances."[3]

In determining whether enhanced damages are appropriate, the Court may consider at least nine factors, enumerated in

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1 35 U.S.C. § 284.

2 *See Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958 (Fed. Cir. 2000) ("While 'a finding of willful infringement does not mandate that damages be increased or that attorneys fees be awarded,' (citation omitted), after an express finding of willful infringement, 'a trial court should provide reasons for not increasing a damages award or for not finding a case exceptional for the purpose of awarding attorneys fees (citation omitted).").

3 *Read Corp. v. Portec. Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992), *abrogated in part on other grounds by Markman v. Westview Insts., Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

Read Corp. v. *Portec, Inc.*[4] This Court has considered the *Read* factors carefully and concludes that enhanced damages doubling the jury verdict are appropriate, such that plaintiff CTI will be awarded an additional $1,019,365.01.

The Court may also award attorney fees for willful infringement "in exceptional circumstances."[5] A finding of willfulness "may be a sufficient basis in a particular case for finding the case 'exceptional' for purposes of awarding attorney fees to the prevailing patent owner."[6]

Plaintiff CTI bears the burden of "establishing entitlement to the award and documenting the appropriate hours expended and hourly rates."[7] Plaintiff has stated that the amount to be awarded will be established by affidavit submitted by counsel. The Court will consider Plaintiffs' request for attorney fees when it submits an affidavit.

Plaintiffs also move for a preliminary injunction pursuant to the Patent Act, 35 U.S.C. § 283. Plaintiffs seek to enjoin LabCorp from performing "any homocysteine-only test,

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4 *Id.* at 827. These nine factors are: (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; (3) the infringer's behavior as a party to the litigation; (4) defendant's size and financial condition; (5) closeness of the case; (6) duration of defendant's misconduct; (7) remedial action by the defendant; (8) the defendant's motivation for harm; (9) whether the defendant attempted to conceal its misconduct.

5 35 U.S. § 285.

6 *Avia Group Intern., Inc.* v. *L.A. Gear California, Inc.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988) (citations omitted).

7 *See Mares* v. *Credit Bureau of Raton*, 801 F.2d 1197, 1201 (10th Cir. 1986) (quoting *Hensley* v. *Eckerhart*, 461 U.S. 424 (1983)).

including without limitation homocysteine-only tests via the Abbott method." "It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it."[8] This Court finds no sound reason for denying the injunction.

Finally, Plaintiffs move for prejudgment interest. An award of prejudgment interest is appropriate in patent infringement actions "absent some justification for withholding such an award."[9] "The purpose of prejudgment interest is solely to compensate the patentee for the loss of the use of royalty income the patentee would have been paid."[10] The rate awarded on the interest is within the discretion of the Court.[11]

The Court will award prejudgment interest to Plaintiff Metabolite based on an interest rate of 8% compounded annually, pursuant to Colo. Rev. Stat. § 5-12-102. The Court will not allow LabCorp, which breached the License Agreement, the benefit of the agreement's 60-day grace period in calculating the date each payment was due. Therefore, Metabolite's request for $473,946.97 will be granted.

As for Plaintiff CTI, the rate of prejudgment interest for patent infringement actions is not provided for in the Patent Act.[12] The Court determines that the 8% interest rate

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8 *Richardson* v. *Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989) (citation omitted).

9 *General Motors Corp.* v. *Devex*, 461 U.S. 648 (1983).

10 *Micro Chemical Inc.*, v. *Lextron, Inc.*, 161 F.Supp.2d 1187, 1210 (D. Colo. 2001) (citing *General Motors Corp.*, 461 U.S. at 654 (1983).

11 *Uniroyal Inc.*, v. *Rudkin-Wiley Corp.*, 939 F.2d 1540, 1545 (Fed. Cir. 1991).

12 *See* 35 U.S.C. § 284.

provided under Colo. Rev. Stat. § 5-12-102 is appropriate for CTI's award as well. CTI will be awarded $132,264.27. Therefore, it is

ORDERED that Defendant's Motion To File Corrected Memorandum In Support Of Laboratory Corporation of America Holding's Renewed Motion For Judgment As A Matter Of Law is granted. It is

FURTHER ORDERED that the clerk shall file stamp the tendered memorandum. It is

FURTHER ORDERED that Defendant's Renewed Motion For Judgment As A Matter Of Law is denied. It is

FURTHER ORDERED that Defendant's Alternative Motion For A New Trial is denied. It is

FURTHER ORDERED that Defendant's Motion To Alter Or Amend Judgment is denied. It is

FURTHER ORDERED that Defendant's Motion To Take Judicial Notice In Support Of Renewed Motion For Judgment As A Matter Of Law And In Opposition To Plaintiffs' Motion For A Permanent Injunction And Rule 7.1 Certification is denied. It is

FURTHER ORDERED that Plaintiffs' Motion For Enhanced Damages And Attorney Fees For Willful Infringement is granted as to enhanced damages to Plaintiff CTI in the amount of $1,019,365.01 and will be considered as to attorney fees upon submission of an affidavit from counsel. It is

FURTHER ORDERED that Plaintiffs' Motion For Permanent Injunction is granted. It is

FURTHER ORDERED that Plaintiff Metabolite Laboratories, Inc.'s Motion To Confirm Prejudgment Interest is granted in the amount of $473,946.97. It is

FURTHER ORDERED that Plaintiff Competitive Technologies, Inc's Motion For Prejudgment Interest is granted in the amount of $132,264.27. It is

FURTHER ORDERED that Defendant's Motion For Stay Of Execution Pending Disposition Of Post-Trial Motions is denied as moot. It is

FURTHER ORDERED that the judgment will be amended to reflect the additional amounts above.

DATED at Denver, Colorado, this 19 day of November, 2002.

BY THE COURT:

/s/
ZITA L. WEINSHIENK,
Senior Judge
United States District Court

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 03-1120
DCT-99-Z-870

METABOLITE LABORATORIES, INC.
AND COMPETITIVE TECHNOLOGIES, INC.,
Plaintiffs-Appellees,

v.

LABORATORY CORPORATION OF AMERICA HOLDINGS
(doing business as LABCORP),
Defendant-Appellant.

ORDER

Filed on August 5, 2004

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on August 12, 2004.

For the court,

/s/ Jan Horbaly
Clerk

APPENDIX D

PERTINENT STATUTORY PROVISIONS

35 U.S.C. § 112 provides in pertinent part:

§ 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

* * * *

35 U.S.C. § 271 provides in pertinent part:

§ 271. Infringement of patent

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.